Bristol-Myers Squibb Company
U.S. Pharmaceuticals

777 Scudders Mill Road Princeton. NJ 0X331-4500
609 897-3213 Fax: 609 897-6067

Petur O. Hansson
Assistant Counsel

December 23, 1999

3729 '99 DEC 23 P2:18

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive
Room l-23
Rockville, MD 20857

## CITIZEN PETITION

The undersigned, on behalf of Bristol-Myers Squibb Company (BMS), submits this petition pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act, and 21 C.F.R. § 320, to request the Commissioner to refrain from finalizing the Draft Guidance for Industry entitled "Topical Dermatological Drug Product NDAs and ANDAs -- In Vivo Bioavailability, Bioequivalence, In Vitro Release, and Associated Studies." This petition replaces BMS' earlier petition, 98D-0388/CP1, which is being withdrawn simultaneous to this submission.

### *A. Action Requested*

BMS requests that FDA not finalize its Draft Guidance for Industry entitled "Topical Dermatological Drug Product NDAs and ANDAs -- In Vivo Bioavailability, Bioequivalence, In Vitro Release, and Associated Studies" (Docket No. 98D-0388) ( "the Guidance") unless and until important outstanding scientific issues related to the Guidance are resolved.

### *B. Statement of Grounds*

In June 1998, FDA issued the Guidance as a draft for comment. The Guidance was met by wide-spread opposition from the scientific community, based on significant scientific and regulatory concerns. BMS believes that the Guidance is based on scientific assumptions that lack support.

This petition will not restate all of the scientific concerns raised in citizen petitions and comments previously filed to Docket No. 98D-0388, and expressed in letters sent to

98D-0388

CP3

Center for Drug Evaluation and Research Director Janet Woodcock, M.D. Rather, BMS wishes to endorse the concerns raised by the American Academy of Dermatology in its letter to Dr. Woodcock and in comment letters submitted to docket 98D-0388 by the Pharmaceutical Research and Manufacturers Association (PhRMA), Johnson & Johnson, Novartis, Spear Pharmaceuticals, and Dermik Laboratories, as well as the citizen petition submitted by Ortho Dermatological.

Because important questions regarding the Guidance have been raised that remain unanswered, we believe that issuance of the Guidance in final form at this time is clearly premature, and presents important substantive scientific concerns. FDA should properly consider the many scientific objections already raised to the Guidance and thoroughly test dermatopharmacokinetics (DPK) and the assumptions underlying its use before any implementation of the Guidance actually occurs.

### *C. Environmental Impact*

The action requested is subject to a categorical exclusion from environmental assessment under 21 U.S.C. § 25.30(h).

### *D. Economic Impact*

Pursuant to 21 C.F.R. § 10.30(b), BMS will provide data concerning the economic impact of the action requested should such information be requested by FDA.

### *E. Certification*

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Petur O. Hansson/mz

Petur 0. Hansson
Bristol-Myers Squibb Company